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REMARKS

Claims 1-43 were pending prior to this Response, with claims 11-43 being withdrawn due to a restriction requirement. By the present amendment, Paragraph 0006 on page 2 of the Specification has been amended to correct an obviously inadvertent grammatical error. In addition, claims 11-43 have been cancelled without prejudice, new claim 44 has been added, and claims 1 and 7-10 have been amended to define Applicant's invention with greater particularity. No new matter has been added, the new claim language being fully supported by the Specification and original claims.

The Objection to the Claims

Applicant respectfully traverses the rejection of claim 1 for containing "of" incorrectly placed between "within" and "the". By the present communication, claim 1 has been amended to delete the "of", thereby obviating the grounds for the objection. Accordingly, reconsideration and withdrawal of the objection to claim 1 are respectfully requested.

The Rejection under 35 U.S.C. § 112, Second Paragraph

Applicant respectfully traverses the rejection of claims 7-10 under 35 U.S.C. § 112, Second Paragraph, as allegedly being indefinite. With regard to claim 7, the Examiner alleges that the phrase "capillaries are fused together to form the array" is a method step so that the structural limitation imposed by the phrase is unclear in a composition claim. Claim 7 has been amended to substitute for the phrase at issue with the phrase "capillaries are held together by being fused together", thus overcoming the grounds for rejection of claim 7.

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With regard to claim 8, the Examiner asserts that the phrase “are formed at intervals” is unclear because it is allegedly a method step “of forming.” To overcome the rejection, claim 8 has been amended to delete “formed” as suggested by the Examiner. Accordingly, reconsideration and withdrawal of the rejection to claim 8 are respectfully requested.

With regard to claim 9, the Examiner asserts that the phrase “are formed at edges” is unclear because it is allegedly a method step “of forming.” To overcome the rejection, claim 8 has been amended to delete “formed” as suggested by the Examiner. Accordingly, reconsideration and withdrawal of the rejection to claim 9 are respectfully requested.

With regard to claim 10, the Examiner asserts that the phrase “are formed of glass” is unclear because it is allegedly a method step “of forming.” To overcome the rejection, claim 10 has been amended to substitute “comprise” for “are formed of” as suggested by the Examiner. Accordingly, reconsideration and withdrawal of the rejection to claim 10 are respectfully requested.

In view of the amendments, Applicant respectfully submits that claims 1-10 meet all requirements under 35 U.S.C. § 112, second paragraph and reconsideration and withdrawal of the rejection are respectfully requested.

The Rejection under 35 U.S.C. § 102

Applicant respectfully traverses the rejection of claims 1-7 and 10 over L. Millstein (WO 99/19711; hereinafter “Millstein”) under 35 U.S.C. §102. For anticipation, a reference must teach each and every aspect of the claimed invention either explicitly or impliedly. M.P.E.P. §706.02. Applicant submits that the invention sample screening apparatus, as defined by amended claim 1, distinguishes over the disclosure of Millstein by requiring “a plurality of

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capillaries held together in an array, wherein each capillary comprises at least one wall defining a lumen for retaining a sample; and interstitial material disposed between adjacent capillaries in the array.”

The Examiner’s rejection is based upon Millstein’s requirement of “providing a plurality of array members.” It is respectfully submitted that the Examiner has misunderstood Millstein regarding the meaning of the terms the “Structural Members” and “Array Members” as used by Millstein. Although Millstein states that “Array members may be anything to be arrayed,” Applicant submits that this statement is misleading when correlation is made to the language of Applicant’s claims. As used by Millstein, an array member is an analyte or sample. For instance, to give just a few examples, array members may be atoms, molecules, thin films....” (page 11, lines 18-21). Thus a plurality of array members is a plurality of samples that will be subject to testing, rather than a plurality of capillaries.

Millstein’s term “structural members” refers to “containers,” not interstitial material, as the Examiner suggests. For example, Millstein states: “Fluid array members, such as solutions, thus generally must be put into a container to give them an appropriate shape and to align them. Structural members is the term used primarily herein for structures, such as containers, that provide support for array members, particularly so they can be aligned and assembled into bundles.” (page 14, lines 28-32) The array members of Millstein (if a structural member is not needed) or the structural members (if the array member is liquid) are “aligned in a bundle” (see Figs. 2-4, and page 16, lines 18-35).

Applicants respectfully submit that Millstein fails to disclose “an interstitial material disposed between adjacent capillaries in the array, as required in the invention sample screening apparatus. When Millstein refers to “analyte binding reagents (ABRs)” (page 26, lines 8-17), the reference is to the case wherein the samples are not liquid and “structural members” are not

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used. Rather, solid samples are directly bound together for analysis. In the case where the array members are contained within “structural members” making up a bundle, Millstein fails to mention any type of interstitial material between the “structural members”. Thus, Millstein fails to disclose the invention apparatus, which comprises a plurality of capillary tubes held together in an array with interstitial material disposed between adjacent capillaries in the array.

Therefore, Applicant respectfully submits that Millstein fails to disclose each and every element of the invention sample screening apparatus, as defined by amended claim 1 (and claims 2-7, and 10 dependent thereon), as would be required to establish anticipation under 35 U.S.C. § 102, and reconsideration and withdrawal of the rejection are respectfully requested.

The Rejection under 35 U.S.C. § 103

Applicant respectfully traverses the rejection of claims 1-10 under 35 U.S.C. §103 as allegedly being unpatentable over the combined disclosures of Dehlinger (U.S. Patent No. 5,763,263, hereinafter “Dehlinger”) in view of Winkler et al. (U.S. Patent No. 5,677,195; hereinafter “Winkler”). Applicant respectfully submits that the invention sample screening apparatus, as defined by amended claim 1, is distinguished over the combined disclosures of Dehlinger and Winkler.

As acknowledged by the Examiner, Dehlinger fails to disclose a positionally addressable array (Office Action, page 5). Instead, Dehlinger discloses an array of capillary tubes wherein the reagent is synthesized, such as DNA, while attached to the interior of the capillary tubes. Thus, while Dehlinger discloses use of capillary action to repetitively “imbibe” individual monomers (e.g., nucleotides) to be used in synthesis of the reagents, Dehlinger neither discloses nor suggests that the synthesized molecule, which necessarily has much greater molecular weight than the individual monomers of which it is built, can be “retained” within capillaries by

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capillary forces because Dehlinger's initial monomers are *attached* to the interior of the tubes making up the array. In particular, Dehlinger fails to suggest that the capillaries of the array are dimensioned for capillary loading with cells for incubation within the tubes of the array in the presence of a "substrate" and/or for interaction of the "substrate" and a recombinant clone or cell to produce a detectable signal.

Winkler does not cure the above-described deficiencies in Dehlinger for teaching or suggesting the claimed invention apparatus. The Examiner relies upon Winkler for disclosing that "reference indicia are essential for consistent and precise positionally addressable array construction and use" (Office Action, page 6). However, in view of the amendments provided by the present communication, amended claims 1-7 do not pertain to "reference indicia." Thus the following remarks address the rejection with respect to new claim 44 and claims 8-10 dependent thereon.

The array disclosed by Winkler is not an array of capillaries, but is instead a flat, optionally rotatable "substrate" having discrete "reaction regions" defined thereon into which a series of monomers are sequentially deposited to fabricate a substance for testing. For example, Winkler teaches that "reagents are delivered to the substrate by either (1) flowing within a channel defined on predefined regions or (2) 'spotting' on predefined regions" (Col 8, lines 64-67). Alternatively, a single molecule, such as a "receptor" can be attached to each region of the substrate and then subjected to a battery of putative binding agents or ligands for the receptor. Because Winkler discloses that array components are deposited at locations on a two dimensional array from pipettes or flow-through channels, there is no suggestion in Winkler of an array of capillary tubes or of tubes dimensioned to load *and retain* by capillary action an analyte, for example a substrate and at least one clone (e.g., a cell for cultivation within the

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capillary tube). Thus, Winkler does not cure the deficiencies of Dehlinger for suggesting the invention apparatus, as defined by amended claim 1.

Nor do the references themselves suggest modification of Dehlinger's capillary array to provide the invention position-addressable capillary array in which interstitial material is disposed between adjacent capillaries because neither reference refers to or suggests interstitial material placed between adjacent capillaries in an array, whether the interstitial material is marked with reference indicia or not. In addition, Winkler's disclosure regarding a positionally addressable flat substrate upon which molecules are synthesized in a grid pattern appears to be "addressable" only in the sense that certain areas of the substrate where light paths intersect are brighter than others, indicating the presence of a particular oligomer formed there (See Section D Channel Matrix Hybridization Assay, Col 29-30). Thus, it is the position of the Applicant that even if the combined disclosures of Dehlinger and Winkler can be said to suggest creation of a position-addressable array, the subject matter of present claims 1-10 and 44 is not suggested under 35 U.S.C. § 103. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. Applicant respectfully traverses the rejection of claims 8, 9 and 10 under 35 U.S.C. §103 as allegedly being unpatentable over the combined disclosures of Dehlinger in view of Winkler et al. Applicant respectfully submits that the invention sample screening apparatus, as defined by claims 8, 9 and 10 (which contain all limitations of claim 1 from which they depend), are distinguished over the combined disclosures of Dehlinger and Winkler.

The deficiencies of Dehlinger discussed above for disclosing the invention apparatus, as defined by claim 1, apply equally and are incorporated here. As acknowledged by the Examiner, Dehlinger fails to disclose or suggest that the interstitial material can comprise one or more

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reference indicia (Office Action, page 5). In addition, Applicant submits that Dehlinger's disclosure with regard to "mapping" of area for deposit of analytes onto a flat surface fails to disclose or suggest a capillary array wherein the sample is retained within the capillaries of the array by capillary forces as discussed above.

Applicant submits that Winkler fails to overcome the deficiencies of Dehlinger for suggesting the invention apparatus, as defined by claim 1 and by dependent claims 8, 9 and 10. To overcome the deficiencies of Dehlinger with regard to Applicant's claims 8 and 9, the Examiner relies on Winkler as disclosing an array comprising reference indicia formed at array intervals (i.e. local) and at edges (i.e. global) ... for the expected benefits of consistent and precise array construction and use ..." (Office Action, page 7). However, the Examiner has provided no reasoning that would support an argument that Winkler suggests how to modify the array of Dehlinger to provide indicia that would be useful in an array of capillaries. Accordingly, Applicant respectfully submits that *prima facie* obviousness under 35 U.S.C. § 103 of claim 1 and dependent claims 8, 9, 10 and new claim 44 is not established over the combined disclosures of Dehlinger and Winkler, and reconsideration and withdrawal of the rejection are respectfully requested.

C. Additionally, Applicant respectfully traverses the rejection of claims 8 and 9 under 35 U.S.C. § 103 (a) for allegedly being unpatentable over Millstein in view of Winkler. The remarks above concerning the Examiner's misinterpretation of Millstein as applied to the present invention apply equally and are incorporated here. In particular, the Examiner's confusion in equating the invention "capillaries" and "interstitial material", respectively, with Millstein's "array members" and "structural member" is carried over in the rejection here (Office Action, page 8). In addition, since Millstein is silent regarding "interstitial material" between capillaries,

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Applicant submits that Winkler's remarks regarding reference indicia on a flat substrate fails to suggest placing reference indicia on interstitial material between capillaries in a capillary array. According, reconsideration and withdrawal of the rejection of claims 8 and 9 for being unpatentable over the combined disclosures of Millstein and Winkler are respectfully requested

The Double Patenting Rejection

Claims 1-10 are provisionally rejected under 35 U.S.C. 101 as allegedly claiming the same invention as that of claims 1-10 of copending Application Serial No. 09/790,321. Since the rejection is only provisional, Applicant elects to defer response to the rejection until such time as claims are allowed in either the present application or in copending Application Serial No. 09/790,321, thus allowing Applicant to cancel the claims at issue from one of the applications without prejudice.

In view of the above amendments and remarks, Applicants respectfully submit that at all rejections have been overcome and allowance of claims 1-10 and 44 is respectfully requested.

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If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative, Lisa A. Haile, J.D., Ph.D., can be reached at (858) 677-1456.

Respectfully submitted,



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